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APPLICATION NO	. FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,865	10/25/2001	Stefan M. Pallazza	S63.2-9720	9976
490	7590 11/02/2005	EXAMINER		INER
VIDAS, A	ARRETT & STEINKR	NGUYEN, VI X		
6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			ART UNIT	PAPER NUMBER
			3731	
			DATE MAIL ED: 11/02/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		09/682,865	PALLAZZA, STEFAN M.			
		Examiner	Art Unit			
	·	Victor X. Nguyen	3731			
	The MAILING DATE of this communication app	1				
Period fo						
WHIC - Exter after - If NC - Failu Any (	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  rill apply and will expire SIX (6) MONTHS from  cause the application to become ABANDONEI	I.  lety filed  the mailing date of this communication.  O (35 U.S.C. § 133).			
Status						
1)🛛	Responsive to communication(s) filed on 12 Au	<u>ıgust 2005</u> .				
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	ion of Claims					
5)□ 6)⊠ 7)⊠	Claim(s) <u>1-9,11,12,14,22,25,26,28,29 and 64-6</u> 4a) Of the above claim(s) <u>10,13,15,20,21,24,27</u> Claim(s) is/are allowed. Claim(s) <u>1-6,11,12,14,22,25,26,28,29 and 64-6</u> Claim(s) <u>7-9</u> is/are objected to. Claim(s) are subject to restriction and/or	<u>and 30-63</u> is/are withdrawn from 67 is/are rejected.				
Applicati	ion Papers					
9) 🗆	The specification is objected to by the Examine	r.				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11)	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex					
Priority (	under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice 3) Information	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) ter No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

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### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-4,6,11-12 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear how the inflatable members constructed and arranged (assumedly by itself?) such that "no contacting portion encircles the balloon catheter."

## Claim Rejections - 35 USC § 102

- 3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
  - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,11-12,14,22,25-26,28-29 and 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (U.S. 5,899,917).

Edwards et al disclose in Figs. 7 and 8a, a device for configuring an inflatable balloon of a balloon catheter assembly having the limitations of the above listed claims, including: a body comprises a plurality of inflatable members (810,820) defining a channel. Each inflatable member has a balloon contacting portion. In fact, Edwards et al disclose in fig. 8a, quite clearly, the inflatable members (810,820) constructed and arranged such that no contacting portion

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encircles the balloon catheter. As to claims 2-6, 11-12,22 and 65-67, Edwards et al disclose the device comprises at least three inflatable members (fig.7). The inflatable members are tubular and have a circular cross section. The device further has a rigid tube (760). The tube has a first end with a first opening and a second end with a second opening that has a passage therethrough; and where the plurality of inflatable members are disposed in one spiral about the channel (figs.7 and 8a), where the balloon contacting portion is made of a compliant material and non-compliant materials such as latex, PET, Polyethylene or silicone (see col. 20, lines 60-62 and col. 22, lines 53-55), and where the body is disposed between first and second end supports, where the first and second end supports are joined by a plurality of connecting members that are spaced apart from the body (fig. 3g)

As to claims 25-26 and 28-29, Edwards et al disclose in Figs.7 and 8a, a method for configuring an inflatable balloon of a balloon catheter assembly having the limitations of claims 25-26 and 28-29, including: a body comprises a plurality of inflatable members (810,820) defining a channel. Each inflatable member has a balloon contacting portion. In fact, Edwards et al disclose in fig. 7 that the inflatable members are capable of inflating inward into the channel so as to reduce a cross section of the channel which extends perpendicular to a longitudinal axis of the channel.

### Allowable Subject Matter

4. Claims 7-9 which depend on claim 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in

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combination, discloses all of the limitations of claim 7 including, the device further comprises first and second end caps, where the first end cap disposed at the first end of the tube across the first opening and the second end cap disposed at the second end of the tube across the second opening.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### Response to Arguments

5. Applicant's arguments with respect to claims 1,5,14,25,28 and 64 have been considered but they are not persuasive. Applicant is asked to please refer to the modified prior art rejection above where examiner addresses applicant's concerns regarding prior art rejections.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen Examiner Art Unit 3731

Vn (1)
10/31/2005

Julian M-Moo

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